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**Commonwealth of Massachusetts  
Betsy Lehman Center for Patient Safety and Medical Error  
Reduction  
Expert Panel on Weight Loss Surgery**

**Frequently Asked Questions - Patient Primer**

**December 12, 2007**

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## **WEIGHT LOSS SURGERY PATIENT PRIMER AND FREQUENTLY ASKED QUESTIONS.**

### **THE ISSUE**

Obesity is a major health problem in the United States and its incidence has reached epidemic proportions. One of every three U.S. adults is considered obese<sup>1</sup> and 1/3 of American children are obese or at risk for developing this serious, complex, chronic disease.<sup>2</sup> People with unhealthy body weight are at increased risk for such illnesses as high blood pressure, heart disease, type 2 diabetes, stroke, osteoarthritis, respiratory problems, sleep apnea, and certain types of cancer. In 2000, approximately 360,000 deaths were attributed to obesity-related diseases.<sup>3</sup>

In addition to the toll obesity takes on a person's physical health, one of the most painful aspects of being obese may be the psychological stress a person experiences. In American culture there is a strong emphasis on physical appearance, and attractiveness is often associated with being slim. There is a social stigma associated with being at an unhealthy body weight, which may result in people being discriminated against in education, the workplace, and health care.

People with obesity suffer from a chronic disease that is often difficult to treat. Weight loss surgery (WLS), also known as bariatric surgery, may be an option for those who are severely obese and who have been unsuccessful in attempts to lose weight through nonsurgical treatment, or who suffer from serious obesity-related health problems. As the number of people with severe weight problems has increased, the numbers of WLS procedures have also risen. While only 402 gastric bypass operations were performed in Massachusetts in Fiscal Year 1998, the number climbed to 3,447 in Fiscal Year 2006.

In 2004, the increase in the number of weight loss surgeries (to 3,034) and concern regarding the safety of these procedures prompted the Massachusetts Commissioner of Public Health to request that the Director of the Betsy Lehman Center for Patient Safety and Medical Error Reduction (Lehman Center) convene an expert panel to study weight loss surgical programs and procedures. The 24-member Expert Panel on Weight Loss Surgery included specialists in the treatment of obesity, patient safety, nutrition, medical practice, managed care, pediatrics, nursing, ethics, and a consumer representative. Its 2004 landmark report has been used to define the standard of care for WLS patients in Massachusetts and has been utilized by American College of Surgeons (ACS) in the development of the Bariatric Surgery Network Center Accreditation Program. Since the release of the initial report, the field of bariatric surgery has undergone rapid growth. Additional data have been published, new surgical techniques have been developed, and emerging issues have been identified. The Lehman Center's response has been to reconvene the Expert Panel in 2007 to

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<sup>1</sup> Rand Corporation. Research Briefs. Obesity and Disability: The Shape of Things to Come. [http://www.rand.org/pubs/research\\_briefs/RB9043-1/](http://www.rand.org/pubs/research_briefs/RB9043-1/). 2007. Accessed June 9, 2007.

<sup>2</sup> Desjardins E, Schwartz AL. Collaborating to combat childhood obesity. *Health Aff (Millwood)* 2007;26:567-71.

<sup>3</sup> Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual causes of death in the United States, 2000. *JAMA* 2004;29:1238-45. [Erratum in: *JAMA*. 2005 293:293-4. *JAMA*. 2005 293:298].

review the current literature and update the original recommendations to ensure the safety of patients considering WLS procedures.

*The information in this document is a tool and should not be considered all-inclusive for those who are considering WLS. It will explain the most common WLS procedures, explore the specific criteria required for potential candidates, and hopefully, encourage dialogue between patients and their health care providers. We recommend that you continue to educate yourself, ask questions, and be sure that your sources of information are accurate and reputable.*

## **WHAT IS WEIGHT LOSS SURGERY?**

To gain an understanding of the surgical procedures that are available, and how they promote weight loss, it is a good idea to become familiar with the anatomy of the gastrointestinal tract. Digestion begins in the mouth aided by the help of specific enzymes found in saliva. Once swallowed, food and fluids are propelled through the esophagus, stomach and intestines in a process known as peristalsis. Food and fluids move through the digestive system with the help of specific substances called enzymes. Nutrients, water and minerals from the intake of food are absorbed from the upper end of the small intestine. Undigested parts of the food are propelled to the colon, further digested, and the residual is expelled by the body as a bowel movement.

Surgical procedures for the treatment of obesity have been available since the 1970's. The procedures cause weight loss either by restricting the amount of food you can eat, interrupting the digestive process, which alters the way nutrients are absorbed, or a combination of both techniques.

## **HOW DO WEIGHT LOSS SURGICAL PROCEDURES WORK?**

### **Laparoscopic Roux-en Y Gastric Bypass (LRYGB)**

The most common gastrointestinal WLS performed in the U.S. is the Laparoscopic Roux-en Y gastric bypass (RYGB)<sup>4</sup> (Figure 1, below). The surgery can also be performed through an “open” approach.

In “open” RYGB, a large incision is made in the abdomen to perform the surgery. When the laparoscopic technique is used, several small incisions are made in the abdomen, and a laparoscope connected to a video camera is inserted through the incisions. The physician is then able to perform the procedure assisted by viewing the internal organs on a television monitor.

In both open and laparoscopic Roux-en-Y gastric bypass, the stomach is divided, creating a small pouch that is closed by several rows of staples. The remaining portion of the stomach is not removed but is “bypassed,” and plays a diminished role in the digestive process. A Y-shaped portion of the small intestine is then attached to the pouch. The volume the pouch is capable of holding is approximately one ounce. Weight loss occurs as a result of reduction of calories, alteration in gut appetite hormones, and decreased nutrient absorption.

Benefits identified with both the open or laparoscopic techniques include:

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<sup>4</sup> DeMaria EJ. Bariatric Surgery for Morbid Obesity. N Eng J Med 2007; 356: 2176-83.

- Significant weight loss;
- Improvement in obesity-related health problems (e.g., , cardiovascular disease, hypertension, type 2 diabetes); and
- Reduction in patient death from obesity.

Compared with the open procedure, the laparoscopic approach shortens postoperative recovery time, reduces pain, and has fewer complications, such as wound infection or hernia. *However*, laparoscopic surgery is technically more complex, and it is extremely important that highly trained, qualified laparoscopic weight loss surgeons perform the procedure.

As with all surgical procedures, there are risks associated with bariatric surgery. Complications that may occur with the Roux-en-Y gastric bypass include:

- Pulmonary embolus;
- Gastrointestinal leak;
- Wound infection;
- Postoperative bleeding;
- Small bowel obstruction;
- Deep vein thrombosis;
- Micronutrient deficiencies; and
- Possible weight regain.

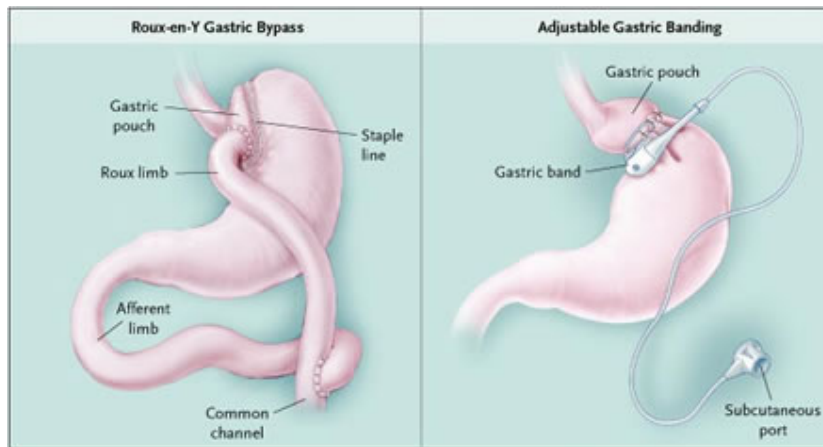
### **Laparoscopic Adjustable Gastric Band Procedure (LAGB)**

The laparoscopic adjustable gastric band procedure (LAGB) is the second most commonly performed WLS. During this procedure, several small incisions are made in the patient's abdomen, and using a laparoscope for guidance, the surgeon places an adjustable band around the upper portion of the stomach. The band is connected to a reservoir that the surgeon can tighten or loosen by infusing varying amounts of a salt solution (Figure 2, below). Weight loss occurs because the newly created upper pouch will only allow the patient to consume small amounts of food at one time.

LAGB has been available since 2001, and research indicates that patients undergoing this procedure have experienced fewer and less severe complications. Complications from LAGB surgery include:

- Slippage of the band;
- Band erosion; and
- Failure to lose or maintain weight loss.

These complications may lead to additional surgical procedures for as many as 20% of patients who undergo LAGB.



**Figure 1**

**Figure 2**

### **Biliopancreatic Diversion (BPD)**

This procedure requires the removal of the lower portion of the stomach. The small pouch that remains is surgically connected to the lower part of the small intestine (Figure 3, below). This procedure results in weight loss because it restricts the amount of food that can be eaten and alters the normal digestive process.

Complications associated with this procedure include:

- Severe protein malnutrition;
- Vitamin deficiencies; and
- Diarrhea.

### **Laparoscopic Sleeve Gastrectomy (LSG)**

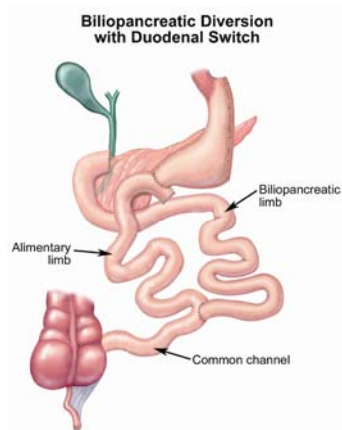
This is a new WLS procedure that may be recommended for patients considered high risk for surgery either because of their weight or underlying medical conditions.

Using a laparoscope, the surgeon removes approximately 60% of the stomach (Figure 4, below). Weight loss occurs because the remaining size of the stomach restricts the amount of food that a person can eat. This procedure may be the first part of a two stage operation. Early reports indicate that it is safe and effective in reducing weight and decreasing obesity-related medical conditions, such as diabetes and high blood pressure.<sup>5,6</sup> Since no long-term data on the safety and effectiveness of the procedure exist, the Expert Panel considers it investigational, but it may be considered if other WLS options are ruled out.

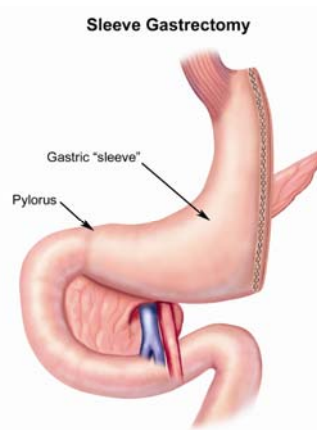
When looking at the risks associated with WLS, it is important to remember that obesity itself carries a high risk of mortality due to obesity-related illnesses. For many patients the potential risks from not having the surgery may be greater than the risks from possible complications of having the procedure.

<sup>5</sup> Kotidis EV, Koliakos G, Papavramidis TS, Papavramidis ST. The effect of biliopancreatic diversion with pylorus-preserving sleeve gastrectomy and duodenal switch on fasting serum ghrelin, leptin and adiponectin levels: is there a hormonal contribution to the weight-reducing effect of this procedure? *Obes Surg* 2006;16:554-9.

<sup>6</sup> Cottam D, Qureshi FG, Mattar SG, et al. Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity. *Surg Endosc* 2006;20:859-63.



**Figure 3**



**Figure 4**

### **WHO SHOULD PERFORM THE SURGERY?**

To promote patient safety and reduce complications, WLS should be performed by highly trained board-certified or board-eligible surgeons who have received documented training in the fundamentals of WLS. Additionally, the Expert Panel recommends that for full privileges, surgeons should:

- Complete a laparoscopic fellowship during which 50 WLS procedures have been performed *or* have been supervised by an experienced weight loss surgeon for at least 25 procedures;
- Successfully complete continuing medical education dedicated to WLS or obesity every two years;
- Have their first 10 cases reviewed by the Chief of Staff and an experienced weight loss surgeon; and
- Count fellowship cases toward individual surgeon volume requirements.

Facilities where WLS is performed should provide a multidisciplinary approach to patient care. Weight loss centers should:

- Be accredited or be in the process of accreditation; and
- Meet WLS volume standards specified by credentialing bodies.

Centers with lower volume should be endorsed if risk-adjusted outcomes fall within benchmarks determined by credentialing body data.

### **AM I A CANDIDATE FOR WEIGHT LOSS SURGERY?**

#### **BODY MASS INDEX (BMI)**

There are many overweight people in the U.S., but not all who are overweight are obese. Obesity is measured by a person's BMI, which is calculated from a person's height and weight. To determine the BMI for an adult 20 years or older click here:

<http://www.cdc.gov/nccdphp/dnpa/bmi/index.htm>

A BMI of < 18.5 means that a person is underweight, while a BMI of 18.5-24.9 is considered normal. A BMI of 25.0-29.9 indicates that a person is overweight. People

with a BMI > 30 have class I obesity. Those with a BMI of 35.0-39.9, have class II obesity, while a person whose BMI is  $\geq 40$  is described as severely obese, or class III obesity. (See Table 1.)

**Table 1. Classification of Obesity**

<b>BMI</b>	<b>CATEGORY</b>
Below 18.5	Underweight
18.5 - 24.9	Healthy
25.0 - 29.9	Overweight
30.0 - 39.9	Obese
Over 40	Severely obese

**Source: National Institutes of Health**

To calculate BMI for children 2 through 19 years click here:

<http://apps.nccd.cdc.gov/dnpabmi/Calculator.aspx>

WLS is not a cosmetic procedure; it is life-altering major surgery. The patient must understand that it will require a commitment to long term/lifelong follow-up care. To be eligible for WLS an adult should meet the following criteria:

- Have a BMI  $\geq 40$  , or BMI  $\geq 35$  with major medical complications of obesity (e.g., cardiovascular disease, type 2 diabetes, sleep apnea);
- Be well-informed and motivated;
- Have a strong desire for substantial weight loss;
- Have failed at nonsurgical approaches to long-term weight loss; and
- Be considered at acceptable operative risk.

### **WEIGHT LOSS SURGERY IN CHILDREN AND ADOLESCENTS**

Certain categories of WLS may be considered for the pediatric/adolescent age group; criteria will usually limit eligibility to children over 12 years of age, provided the following criteria are met:

- Compliance strategies, careful monitoring of vitamin and mineral intake, and periodic laboratory surveillance to detect deficiencies are included in patient care;
- The patient's comprehension of the risks, benefits, and importance of follow-up should be formally evaluated before the patient consents to the surgery;
- A BMI  $\geq 35$  with serious obesity-related diseases, such as type 2 diabetes mellitus or moderate to severe sleep apnea, or a BMI  $\geq 40$  with problems such as high blood pressure, insulin resistance, glucose intolerance, or substantially impaired quality of life or activities of daily living.
- Evaluation and treatment for psychological issues prior to consenting to the surgery;
- Preference for Roux-en-Y gastric bypass; ;
- Demonstrated ability to comply with treatment regimens and medical monitoring prior to WLS;
- Information about increased fertility provided to all female adolescent patients after WLS;



- Information about possible risks associated with pregnancy in the first 18 months after WLS provided to all female adolescent patients, with counseling to avoid pregnancy during this period and an offer of contraception.
- Informed consent separate from the patient's parents, with the parental permission process including a discussion of the risks of adult obesity, available medical treatments, surgical alternatives, and specific risks and outcomes of the proposed WLS in the proposed institution.

Those who should be considered for WLS on a case-by-case basis include:

- A patient with mental retardation, with particular evaluation regarding knowledge, motivation and compliance, and with an ethicist on the evaluation team.
- Patients with syndromic obesity, endocrine disorders, obesity that appears to be related to the use of weight-promoting medications, and those in whom obesity cannot be controlled through medical interventions and/or carefully designed environmental and behavioral management.
- Patients with uncontrolled psychosis, bipolar disorder, or substance use disorders, with case-by-case consideration only after one year of remission.

## **CONTRAINDICATIONS TO SURGERY**

There are some circumstances where the risks of the surgery may outweigh the potential benefits. For example, WLS may be contraindicated for patients with severe pulmonary disease, unstable coronary artery disease, and other conditions that may seriously compromise anesthesia or wound healing. It is recommended that women of child-bearing age be tested for pregnancy before WLS. Women who are pregnant, planning to become pregnant within 18 months, or are currently breastfeeding should not be considered for WLS. Many people considering WLS suffer from Obstructive Sleep Apnea (OSA), and while this is not a contraindication to surgery, it is recommended that they not have WLS as an outpatient.

## **HOW SHOULD I PREPARE FOR SURGERY?**

Prior to surgery patients should receive psychological, nutritional, and medical care to identify and treat potential problems and promote greater understanding of needed long term-treatment. Patients who smoke cigarettes should be encouraged to quit. Those who need help quitting should receive assistance at the facility where the WLS is planned. It is also recommended that all patients lose 5% to 10% of initial body weight preoperatively, if possible. You will be encouraged to increase physical activity before surgery and continue exercising for the rest of your life.

## **EDUCATION**

One of the most important aspects in preoperative preparation for WLS candidates is education. Success of the surgical treatment depends on a highly motivated patient who has realistic goals, is committed to weight loss, and demonstrates a thorough understanding of the procedure, possible complications, lifestyle changes, and medical guidelines that must be followed for the rest of their lives. Patients should be active participants in their own education. They should be encouraged to ask questions, and teaching techniques should be tailored to meet the individual's needs.

Particular attention should be paid to the patient's psychosocial needs. Prior to the surgery, a patient's support system should be identified. Families and friends should

be included in the educational process. Some of the issues that should be explored include the potential impact the surgery may have on relationships, as well as psychological issues a patient may experience after surgery. Patients who suffer from psychological issues related to eating may need to have long-term professional help.

Obesity is a very serious illness, which can lead to many medical complications. For patients who meet strict criteria, WLS is a proven intervention that leads to significant weight loss. In addition, patients can experience improvements in obesity-related diseases, and reduce the risk of premature death.

### **QUESTIONS EVERY WEIGHT LOSS SURGERY CANDIDATE SHOULD ASK THEIR SURGEON**

WLS is major surgery. It can result in improved health, greater quality of life, and a longer life. However, like all surgical procedures it carries a certain amount of risk. As a potential WLS candidate you should be certain that you are aware of all the risks, have researched your options, and are fully educated about the surgical procedure.

While not exhaustive, the following checklist contains questions that should be explored with your surgeon prior to scheduling the procedure. You might find it useful to print this document and take it with you when you see your surgeon. Your surgeon should welcome these questions. If you don't understand the answers, ask your surgeon to repeat and explain things clearly. Remember, an informed, educated patient is more likely to be satisfied with the outcome of the surgery.

- Why do I need surgery?
- What nonsurgical treatments might be appropriate for me?
- How is the surgery expected to improve my health or quality of life?
- Which surgical procedure are you recommending for me?
- Should I try to lose weight before the surgery?
- Do I need a complete physical exam before the procedure?
- Should I stop smoking?
- Is WLS recommended if I am pregnant or plan to become pregnant?
- Do you recommend a psychosocial evaluation?
- Can you explain the operation?
- Can you provide me with a diagram of the surgery?
- Do you have written materials or videotapes about the procedure that I can review?
- What are the short- and long-term risks or complications of this procedure? How often do they occur?
- Do the benefits outweigh the risks?
- Is your weight loss center accredited or in the process of obtaining accreditation?
- What are your credentials? Are you board-certified or board-eligible?
- What is your experience with this surgery, and how many procedures have you performed?
- Have you received special training to perform laparoscopic procedures?
- Where can I get a second opinion?
- Where will the surgery be performed?

- How long can I expect to be hospitalized?
- Does the hospital provide formal education for patients undergoing bariatric surgery?
- Does the hospital have special beds, tables, stretchers and wheelchairs, hospital gowns, and other equipment to accommodate me?
- What type of anesthesia will be used and what are the risks?
- How much pain is normal to expect, and how long will it last?
- Will I receive medication for the pain?
- What complications can arise after surgery? What are the signs of complications? What should I do if they occur?
- How often will I need to return for follow-up visits?
- Will I need to take any medications after the surgery?
- Will I be able to exercise after my surgery?
- After losing a lot of weight, will my skin be loose, and if so, will I need to have plastic surgery to improve its appearance?
- Can you give me the name of someone who has undergone this surgery, and who would talk to me about it?
- Will my insurance cover the procedure, and any surgery- related care needed before and after surgery?
- How can I learn more?